UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.usplo.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

27799 7590 11/23/2010 COHEN, PONTANI, LIEBERMAN & PAVANE LLP 551 FIFTH AVENUE SUITE 1210 EXAMINER
COLEMAN, BRINDA LIBBY
ART UNIT PAPER NUMBER
1624
DATE MAILED: 11/23/2010

| APPLICATION NO.   | FILING DATE                              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |  |  |
|---|--|----------------------|---------------------|------------------|--|--|--|
| 10/591,831  | 10/591,831 10/23/2006 Berta Kotar-Jordan |                      | 4061-34PUS          | 4625             |  |  |  |
| TITLE OF INVENTION: ISOPROPANOL WATER SOLVATE OF OLANZAPINE |  |                      |                     |                  |  |  |  |

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1510        | \$300               | SO.                  | \$1810           | 02/23/2011 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

NEW YORK NY 10176

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

| appropriate. All further<br>indicated unless corrects<br>maintenance fee notifica  | correspondence includir<br>ed below or directed oth  | or transmitting thing the Patent, advantage of the Patent, advantage of the Block 1               | ance orders and no<br>by (a) specifying   | tification of r<br>a new corres   | naintenance fees wi<br>pondence address;   | ill be<br>and/or                            | mailed to the current<br>(b) indicating a sepa   | correspondence<br>rate "FEE ADI  | e address as<br>DRESS" for   |
|--|--|---|---|---|--|---|--|--|--|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)   |  |   |   | Note<br>Feet<br>pape<br>have  | Note: A certificate of mailing can only be used for domestic mailings of the<br>Fee(s) Transmittal. This certificate cannot be used for any other accompanying<br>papers. Each additional paper, such as an assignment or formal drawing, must<br>have its own certificate of mailing or transmission. |   |  |  |  |
| 551 FIFTH AVE<br>SUITE 1210  |  |   | NE LLP  |   | Conti  | ificate                                     | of Mailing or Trans<br>s) Transmittal is being<br>ficient postage for fire<br>ISSUE, FEE address<br>I) 273-2885, on the d    | mission  |  |
| NEW YORK, N  | Y 10176  |   |   |   |  |   |  | (Dep   | positor's name)  |
|  |  |   |   |   |  |   |  |  | (Signature)  |
|  |  |   |   | L   |  |   |  |  | (Date)   |
| APPLICATION NO.  | FILING DATE  |   | FIRST NAME  | FIRST NAMED INVENTOR  |  | ATTORNEY DOCKET NO.                         |  | CONFIRMATION NO.   |  |
| 10/591,831   | 10/23/2006   |   |   | tar-Jordan  |  |   | 4061-34PUS   | 4625   |  |
| TITLE OF INVENTION   | : ISOPROPANOL WAT  | ER SOLVATE OI   | FOLANZAPINE   |   |  |   |  |  |  |
| APPLN, TYPE  | SMALL ENTITY   | ISSUE FEE DU  | E PUBLICATI   | ON FEE DUE  | PREV. PAID ISSUE   | FEE   | TOTAL FEE(S) DUE   | DATE   | DUE  |
| nonprovisional   | NO   | \$1510  | S   | 300   | \$0  |   | \$1810   | 02/23/   | 2011   |
| EXAM   | IINER  | ART UNIT  | CLASS-S   | UBCLASS   | ]  |   |  |  |  |
| COLEMAN, BE  | RENDA LIBBY  | I624  | 540-5   | 557000  |  |   |  |  |  |
| 1. Change of correspondence address or indication of "Fee Address" (37)  CTR 1.363).  Change of correspondence address (or Change of Correspondence Address from PTO/SB/122) attached.  The Address of methods and the Address' Indication (or "Fee Addr |  |   |   |   |  |   |  |  |  |
|  | less an assignee is ident<br>h in 37 CFR 3.11. Comp<br>GNEE  | ified below, no as<br>oletion of this form  | signee data will ap<br>is NOT a substitute<br>(B) RESIDI  | pear on the pe for filing an ENCE: (CITY  | atent. If an assigne<br>assignment.<br>and STATE OR CO   | DUNT  |  |  |  |
| 4a. The following fee(s)  Issue Fee Publication Fee (N   | vo small entity discount p   | permitted)  | A check   | is enclosed.<br>t by credit car   | d. Form PTO-2038   | is atta                                     | riously paid issue fee<br>sched.<br>required fee(s), any de<br>(enclose a  |  | dit any<br>this form).   |
| - 11   | s SMALL ENTITY state   | is. See 37 CFR I.2  | 1.1   |   |  |   | ITTY status. Sec 37 Cl   |  |  |
| NOTE: The Issue Fee an<br>interest as shown by the   | d Publication Fee (if req<br>records of the United Sta   | uired) will not be a<br>tes Patent and Trac   | ccepted from anyor<br>lemark Office.  | ne other than t   | he applicant; a regis  | tered :                                     | attorney or agent; or th   | e assignee or ot   | her party in   |
| Authorized Signature   |  |   |   | _   | Date   |   |  |  |  |
| Typed or printed name  |  |   |   |   | Registration No  |   |  |  |  |
| This collection of inform<br>an application. Confiden<br>submitting the complete<br>this form and/or suggesti<br>Box 1450, Alexandria, V<br>Alexandria, Virginia 223   | nation is required by 37 C<br>tiality is governed by 35<br>d application form to the<br>ions for reducing this but<br>'irginia 22313-1450. DC<br>k13-1450. | FR 1.311. The info<br>U.S.C. 122 and 3<br>USPTO. Time wi<br>rden, should be ser<br>O NOT SEND FEE | ormation is required<br>7 CFR 1.14. This co<br>all vary depending to<br>to the Chief Infor<br>S OR COMPLETE | I to obtain or rollection is est<br>upon the indiversation Office<br>D FORMS TO | etain a benefit by th<br>imated to take 12 m<br>idual case. Any con<br>er, U.S. Patent and T<br>D THIS ADDRESS.  | e publ<br>inutes<br>nment<br>fraden<br>SENI | lic which is to file (and<br>to complete, including<br>s on the amount of the<br>lark Office, U.S. Dep<br>D TO: Commissioner | by the USPTO<br>g gathering, pro<br>ne you require<br>artment of Com<br>for Patents, P.O | to process)<br>eparing, and<br>to complete<br>merce, P.O.<br>Box 1450, |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# UNITED STATES PATENT AND TRADEMARK OFFICE

#### UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

PO Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

| APPLICATION NO.            | FILING DATE    | FIRST NAMED INVENTOR           | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|----------------------------|----------------|--------------------------------|---------------------|------------------|--|
| 10/591,831                 | 10/23/2006     | Berta Kotar-Jordan             | 4061-34PUS          | 4625             |  |
| 27799 7                    | 590 11/23/2010 |                                | EXAM                | UNER             |  |
| COHEN, PONT.               | ANI, LIEBERMAN | COLEMAN, BRENDA LIBBY          |                     |                  |  |
| 551 FIFTH AVEN             | IUE            |                                | ART UNIT            | PAPER NUMBER     |  |
| SUITE 1210<br>NEW YORK, NY | 10176          | 1624<br>DATE MAILED: 11/23/201 | 0                   |                  |  |

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 649 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 649 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

| Application No.   | Applicant(s)   |       |  |
|-------------------|----------------|-------|--|
| 10/591,831        | KOTAR-JORDAN E | T AL. |  |
| Examiner          | Art Unit       |       |  |
| Brenda L. Coleman | 1624           |       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1

- 1. This communication is responsive to the amendment filed November 9, 2010,
- The allowed claim(s) is/are 1-22,24 and 26-32.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) 🔯 All b) ☐ Some\* c) ☐ None of the:
    - 1. T Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
      - 3. \( \overline{\text{Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance

# /Brenda L. Coleman/

Primary Examiner, Art Unit 1624

9. ☐ Other

Application/Control Number: 10/591,831 Page 2

Art Unit: 1624

# EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kent H. Cheng on November 12, 2010.

The application has been amended as follows:

In the Specification:

Please insert the following brief description of the drawings before the heading "DETAILED DESCRIPTION OF THE INVENTION" on page 4:

# -- BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 The x-ray structure of the isopropanol/water mixed solvate of olanzapine; and

Figure 2 The NMR spectrum of the isopropanol/water mixed solvate of olanzapine. --

Application/Control Number: 10/591,831 Page 3

Art Unit: 1624

# Reasons for Allowance

The following is an examiner's statement of reasons for allowance: in view of the Applicants' amendments and the Examiner's Amendment attached herewith the claims are now in condition for allowance. None of the prior art of record or a search in the pertinent art area teaches the in the compounds, process of preparing and the method of use of the isopropanol/water mixed solvate of olanzapine as claimed herein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Application/Control Number: 10/591,831 Page 4

Art Unit: 1624

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/ Primary Examiner, Art Unit 1624